

## REMARKS

### 5    **Amendments to the Drawings and the Specification.**

Replacement sheets 2 and 3 of the drawings are submitted herewith, and corresponding amendments have been made to the description of the drawings in the specification. Applicant recognizes that it will be desirable, even if it is not strictly  
10    necessary, to provide drawings of better quality, and will do so when agreement has been reached on the claims.

### **Amendments to the Claims**

The claims have been amended, and new claims added, to define the  
15    invention more completely. These amendments have been made in the interests of speedy prosecution, and without prejudice to Applicant's right to prosecute different claims in one or more continuing applications.

### **Summary.**

**The first independent claim, claim 17**, has been amended to state (1) that  
20    the container is a shipping container which can be loaded onto and transported by ship or a truck (see page 17, lines 5-6, for basis) and (2) that the module was constructed separately from the shipping container (see page 20, line 19, for basis).

**In the claims dependent on claim 17**, which relate to preferred features, Claim 18 has been amended to require the presence of sensors which are in the  
25    inner atmosphere and whose input changes the rate at which the second atmosphere is supplied; Claim 22 no longer defines the shape of the chamber, but requires flexible conduits which connect to the inlet and outlet of the module; Claim 23 no longer defines the shape of the chamber, but requires that the ACM is a microporous film having a coating of a side chain crystalline polymer, and has an  
30    oxygen P 10 ratio of at least 1.3; and Claims 25-28 and 33 have been amended to place additional requirements on the ACMs in the module.

The **second independent claim, claim 34**, is no longer directed to a method of "making a shipping container as defined in claim 17", but rather to a method of loading a shipping container (thus avoiding any possible implication that the method actually constructs a shipping container), and recites the various restrictions which were implied by the words "as defined in claim 17". In addition, claim 34, like amended claim 17, requires that the container is a shipping container which can be loaded onto and transported by ship or a truck and that the module was constructed separately from the shipping container.

The **amended claims dependent on claim 34, and the new claims 38-44 dependent on claim 34**, relate to preferred features similar to those in the claims dependent on claim 17, and also, in new claims 40-42, to the presence of an auxiliary closed chamber which is different from the closed chamber of the module.

**New independent claim 45** is directed to a method of unloading a loaded shipping container, the loaded shipping container being defined as in amended claim 17. The method of claim 45 comprises the steps of (A) unsealing the enclosure around the respiring biological material, (B) after step (A), removing the module from the enclosure, and (C) after step (B) unloading the respiring biological material. Basis for claim 45 is, for example on page 21, lines 8-11.

**New claims 46-54, dependent on claim 45**, relate to preferred features similar to those in the claims dependent on claim 34.

**New independent claim 55** is directed to a shipping container which contains the limitations of amended claim 17, and requires in addition the presence of an auxiliary closed chamber which is different from the closed chamber of the module. For the avoidance of doubt, it is noted that in claim 55, and likewise in the dependent claims requiring an auxiliary closed chamber, the primary second atmosphere and the auxiliary second atmosphere can be the same or different; for example, both can be air, or one can be air and the other oxygen enriched air.

**New claims 56- 60, dependent on claim 55**, relate to preferred features similar to those in the claims dependent on claim 34.

**Basis for the claim features.**

Basis for the various features introduced in the amended claims is shown in the table below. The claim numbers in **bold** are the independent claims.

Claim #	Feature (summarized)	Basis
17, 34, 45, 55	(1) shipping container which can be loaded onto and transported by a ship or a truck	page 17, lines 5-6, page 21, lines 6-16
17, 34, 45, 55	(2) Module was constructed separately from the shipping container.	Page 20, line 19
34	(3) module is placed in container after respiring biological material	page 21, lines 6-16
45	(4) module is removed from container before respiring biological material	page 21, lines 6-16
22, 35, 46, 60	(5) Flexible conduits	Page 28, lines 10, 12 and 27
18, 44, 54, 56	(6) Sensors and pressure-generating means	page 6, lines 18-19, page 15, line 27-page 16, line 8
25, 36, 47, 55	(7) ACM in module has an R ratio of at least 3.0	Page 13, lines 32-33
23, 33, 38, 48	(8) ACM is a microporous film coated with a polymer, e.g., the ACM is a microporous film having a coating of an SCC polymer, and has an oxygen P 10 ratio of at least 1.3	Page 14, lines 1-2 and 26-29
25, 49, 59	(9) Primary closed chamber has two ACMs	Page 5, lines 10-15, page 10, lines 24-25, page 13, lines 21-22, page 16, lines 20-22, page 19, lines 15-31
40, 50, 55	(10) Auxiliary closed chamber	page 16, lines 12-13,
26, 41, 51, 57	(11) Second ACM has R ratio of 1-2.3, e.g. 1	page 5, lines 10-11, Page 13, lines 12-17, page 16, lines 14-18,
42, 52, 58	(12) Second ACM is porous sheet with no polymer coating	Page 13, lines 1-6
24, 43, 53, 56	(13) Multiple ACM-containing inner containers	Page 8, lines 8-21

## **The Objections to the Drawings**

It is believed that the amendments made to the specification and drawings will overcome the objections to the drawings. As the amended specification makes clear, Figure 8 shows a plurality of containers comprising pinholes (recognizing, however, that, as indicated by the Brief Description of the Drawings, the pinholes are not drawn to scale).

## **The Rejection under 35 USC 112**

The amended claim 34 provides the necessary antecedent basis.

## **The Rejections under 35 USC 103.**

Applicant respectfully traverses the rejections under 35 USC 103, insofar as they are applicable to the amended claims, for the following reasons.

### **1. Marcellin.**

Marcellin is the primary reference in all the rejections. It is a translation of an article in French. As noted below, the translation is in some important respects incorrect.

Marcellin discloses, in particular in Figure 10A on page 231, an ACM-containing "battery" or "exchanger-diffuser", which is "housed inside" what the translation calls a "cooler" containing a respiring biological material. Air is passed through the battery, and gas exchange takes place through the ACM in order to control the atmosphere surrounding the biological material. There are several ACMs in Marcellin's battery. Each ACM has a surface area of 3 m<sup>2</sup> and is composed of a "membrane made from a Tergal "veil" of very fine mesh (52-54 g/m<sup>2</sup>) covered by a continuous, thin and uniformly thick layer (about 90 µm) of silicone rubber (dimethyl polysiloxane)" -- see page 222, left-hand column. The term in the French original which has been translated as "veil" is "voile". That is, however, a mistranslation. The

correct English term is the same as the French term, namely "voile", which is a lightweight woven fabric. Tergal is a trade name for a polyester.

Marcellin makes it clear that the item which the translation calls a "cooler" is a room, i.e. a structure having a fixed and permanent location. For example, at the beginning of the relevant section, on page 230, Marcellin refers to the possibility of using polymer membranes "in the form of enclosures with "defusing walls" (*sic* clearly the correct translation of the corresponding French words, "parois diffusantes", is "diffusing walls"). Similarly, the section entitled Examples of Applications, on page 234, states that the "cooler" is a refrigerated storage depot, i.e. an enclosure which has a fixed and permanent location. The words in the original French language version of Marcellin which have been translated as "cooler" are either "chambre froide" or simply "chambre", and the correct translations of those French words are "cold room," and "room". The term "cooler", taken out of context, might be given a broader meaning than the correct translation, "cold room".

Marcellin's illustration of an internal "battery" shows a structure which is permanently affixed to a side wall of a cold room. Continuous conduits for passing gas into and out of the battery pass uninterrupted through the side wall of the cool room, and form a monolithic structure with the battery itself.

For the avoidance of unnecessary dispute, Applicant agrees that Marcellin's cold room has a capacity of at least 40 m<sup>3</sup> and that Marcellin's battery includes an inlet for incoming gas, an outlet for outgoing gas, and an atmosphere control member having a surface area greater than 0.65 m<sup>2</sup> and comprising first and second surfaces as defined in, for example, claim 17. Similarly, Applicant agrees that it is inherent in Marcellin that the respiring biological materials are loaded into the cold room, after which the cold room is sealed, and that after a period of storage, the cold room is unsealed and the respiring biological materials are unloaded from the cold room. However, Marcellin does not provide any information about the way in which loading and unloading are carried out.

There are numerous features of the claims which distinguish between the claimed invention and Marcellin, either alone or in conjunction with other references. The most important of these differences are discussed below. Applicant does not concede that these are the only significant differences.

**1. Marcellin's Failure to Disclose or Suggest a Shipping Container.**

The first distinguishing feature, which is present in all the claims, is that the invention is directed to a shipping container which can be loaded onto and transported by a ship or a truck. Paragraph 5 of the Office Action, which contains the principal rejection over Marcellin, describes Marcellin as disclosing a "storage container" or "container", without noting that Marcellin relates only to a very particular type of storage container, namely a cold room. Paragraph 5 also makes no comment on the fact that the claims under examination were directed to "shipping containers." Perhaps that was because the Examiner supposed that the word "shipping" in the term "shipping container" did not limit the claims. Applicant thinks that was wrong. However, for the avoidance of doubt ( and as noted above), the claims have been amended to state explicitly that they relate to shipping containers which can be loaded onto and transported by a ship or a truck.

As the summary of Marcellin above makes clear, Marcellin discloses only a storage container which is a cold room having a fixed and permanent location. An essential attribute of a shipping container, by contrast, is that it should be portable. The Office Action does not provide any rationale to support what must be an essential part of any rejection based on Marcellin, namely that one of ordinary skill in the art would have found it obvious to take Marcellin's teaching, which relates only to fixed storage rooms, and apply it to shipping containers. Applicant believes that, for that reason alone, all the rejections under 35 USC 103 should be withdrawn.

**2.. Marcellin's Failure to Disclose a Module**

The second distinguishing feature, which again is present in all the claims, is that the ACM must be part of a module which was constructed separately from the shipping container. Paragraph 5 of the Office Action assumes that Marcellin's battery is a "module". Applicant thinks that was wrong, since Marcellin's battery is an integral part of the cold room, and the accepted meaning of the term "module" (which is reinforced by the disclosure of the specification) is that a module is a separable component that forms part of a larger system. However, for the avoidance of doubt the amended claims state explicitly that the module is constructed separately from the shipping container. The Office Action does not provide any rationale to support an allegation that one of ordinary skill in the art would have found it obvious to take

Marcellin's teaching, which relates only to a fixed battery forming an integral part of a cold room, and apply it to a separately constructed module

**3. Marcellin's Failure to Disclose the Loading and Unloading Procedures Defined in Claims 34 and 45 .**

The significance of the differences noted in paragraphs 1 and 2 above is highlighted by independent claims 34 and 35. Thus, claim 34, which is directed to loading a shipping container, requires that the module should be placed in the container **after** the respiring biological material has been loaded into the container; and claim 45, which is directed to unloading a shipping container and requires that the module should be removed from the container **before** the respiring biological material. In those methods, the module must of course be separable from the shipping container. Marcellin's battery, by contrast, is fixed permanently to the wall of the cold room. Marcellin's battery, therefore, **must** be in the cold room while the respiring biological material is being loaded into the cold room, and **cannot** be removed from the loaded cold room before the respiring biological material is unloaded from it.

The Office Action, in rejecting claim 34, notes that claim 34 differs from Marcellin in reciting that the module is placed in the container after placing the respiring biological material, but then comments

*... whether the module was first placed into the container or was placed into the container after placing the respiring biological material therein would have been an obvious rearrangement of steps that would not have provided a patentable distinction over the prior art.*

This comment, however, ignores the simple fact that Marcellin's battery is fixed to the walls of the cold room, and that there is nothing in Marcellin or the other references to suggest the procedures required by claims 34 and 45, or that the battery should be portable for any reason. Nor has the Examiner suggested that there is any "common sense" reason why one of ordinary skill in the art would have motivated to modify Marcellin's disclosure in a way that might lead to the loading and unloading procedures of claims 34 and 45. Applicant believes that it is only with knowledge of Applicant's invention that hindsight might suggest that there could be

advantages in the loading and unloading procedures defined in claims 34 and 45. There are indeed such advantages, since Marcellin's battery, being present in the container during loading and unloading, puts constraints on the loading and unloading, and must be protected from damage, whereas Applicant's module avoids those difficulties.

**4. Marcellin's Failure to Disclose Flexible Conduits as in claims 22, 35, 46 and 60.**

Also relevant to the differences noted in paragraphs 1-3 above are the new dependent claims 22, 35, 46 and 60, which specify that the inlet and outlet are connected by flexible conduits (again, a feature not disclosed or suggested by Marcellin). The use of flexible conduits simplifies the installation and removal of the module.

**5. Marcellin's Failure to Disclose Sensors and Pressure Generating Means, as in Claims 18, 44, 54 and 56.**

Thé Office Action relied on De Moor and Liston to make good Marcellin's failure to disclose sensors and pressure generating means as in claims 18, 44, 54 and 56. They do not do so. In De Moor, the oxygen sensors merely record, for test purposes, oxygen levels in an enclosure having an atmosphere control member.. They do not in any way control the delivery of a second atmosphere to the atmosphere control member. Quite apart from that, it is hard to imagine how De Moor could make use of an ACM having an area of at least a 0.65 m<sup>2</sup>. Liston is concerned with a completely different technology, in which air is pretreated in a gas separation means comprising a plurality of hollow fiber membranes. The treated gas is then delivered to the storage facility -- see for example, column 6, lines 42-62, and Figures 3-8 and the description of them. The hollow fiber membranes are not exposed to the gas surrounding the product in the storage facility.

**6. Marcellin's Failure to Disclose combinations of ACMs as required by claims 25-27, 39, 40-42, 49-52 and 55-59.**

The Office Action relied on various references to make good Marcellin's failure to disclose the combinations of ACMs which were the subject of the dependent claims under examination. In the interest of speedy prosecution, the



amended claims set out more specific combinations of particular ACMs.

Independent claim 55 and dependent claims 40 and 50, in particular, require the presence of a module which contains a primary closed chamber comprising a primary ACM having an R ratio of at least 3 and an auxiliary closed chamber  
5 comprising an auxiliary ACM having a ratio of 1.0-2.3, preferably 1 (claims 41, 51 and 57)

**7. Marcellin's failure to disclose the use of a module containing an ACM which (i) has an oxygen P 10 ratio, over at least one 10°C range between -5 and 15°C, of at least 1.3, and (ii) a microporous film having a coating of a side  
10 chain crystalline polymer, as required by claims 23, 33, 38 and 48.**

Applicant has found such ACMs to be particularly useful. The ACM used by Marcellin comprises a **woven** substrate coated with a polysiloxane. Polysiloxanes are not side chain crystalline polymers, and are not crystalline, and cannot, therefore, have a P 10 value as specified.

**15 8. Marcellin's failure to disclose that the respiring biological material is packed in a plurality of ACM-containing sealed inner containers, as in claims 24 and 43.**

The Office Action, in paragraph 6, relies upon Clarke and De Moor as disclosing that the respiring biological material is placed in a plurality of ACM-  
20 containing sealed inner containers. Paragraph 43-46 of Clarke do indeed refer to a plurality of ACM-containing containers, each containing a respiring biological material, with those ACM-containing containers being placed in "a shipping or trucking container, which may be a closed container, or open container". Clarke does not, however, disclose or suggest that the shipping or trucking container should  
25 contain an additional ACM of any kind, still less an ACM which is part of a module through which a second atmosphere is passed. De Moor discloses only a single ACM-containing container and there is again the problem that De Moor clearly cannot be used with an ACM having an area of at least 0.65 m<sup>2</sup>. In both references, the atmosphere control within the container(s) results solely from the ACM that  
30 forms part of each container. In the invention claimed in claims 24 and 43, by contrast, the atmosphere control around the respiring biological material results from a **combination** of the ACM in the inner container and the ACM in the module (see

for example page 18, lines 11-13, page 20, lines 10-13, and page 22, lines 11-page 23, line 10, of the substitute specification. The Office Action does not provide any rationale to support the assertion that it would have been obvious to modify Marcellin by placing the respiring biological material in a plurality of sealed inner packages, each containing an ACM. There is nothing in Clarke or De Moor to suggest that one of ordinary skill in the art would have found it obvious to create the novel atmosphere control system which results when multiple ACM-containing containers are placed in a larger container which is itself subject to atmosphere control. Still less is there anything in Clarke or De Moor to suggest taking this step in conjunction with Marcellin's disclosure. It is only with the benefit of hindsight that it is possible to make the allegation which supports the rejection of these claims.

#### **The Provisional Double Patenting Rejections.**

Since it is not clear what claims will be allowed in this application or in co-pending application 11/989,513, Applicant will give proper consideration to these rejections when it is clear what claims will be allowed in the two applications.

#### **Conclusion**

It is believed that this application is now in condition for allowance, and such action at an early date is requested. If, however, there are any remaining objections or rejections that could usefully be discussed by telephone, the Examiner is asked to call the undersigned.

Respectfully submitted,



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